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Award Number: W81XWH-08-1-0057

TITLE:

The development of prostate palpation skills through simulation training may impact early detection of prostate abnormalities and early management

PRINCIPAL INVESTIGATOR: Gregory J. Gerling, PhD

CONTRACTING ORGANIZATION: University of Virginia Charlottesville, VA 22904

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Table of Contents

	Page
Introduction	4
Body	5
Key Research Accomplishments	17
Reportable Outcomes	18
Conclusion	18
References	18
Appendices	18

Introduction

Our team is composed of the PI, Gregory J. Gerling, PhD, School of Engineering and two co-Is Reba Moyer Childress, MSN, FNP, School of Nursing and Marcus L. Martin, MD, School of Medicine. We have been working with three graduate students (Angela Lee, William Carson, and Elmer Kim) during this reporting period and with two others (Leigh Baumgart and Ninghuan Wang) in the past. We have also brought in two undergraduate students (Petheree Norman and Tashima Lambert). During this reporting period, we have developed working collaborations with Tracey Krupski, MD, School of Medicine (Urology) and Randy Jones, School of Nursing – both of whom have particular expertise as relates to prostate cancer and disease. We have worked also in conjunction with O. John Semmes, PhD, Eastern Virginia Medical School (EVMS) and Beatriz Lopes, MD, University of Virginia, Autopsy Services.

The following series of aims and tasks had been laid out in the grant application according to the timeline. We discuss in the body of the document our progress toward achieving those.

Aim 1. Determine distinct skill levels for discernment of palpable characteristics.

<u>Task 1.a)</u> Characterize anatomical attributes and pathological stages of disease.

Task 1.b) Determine the range of disease states that are palpable and simulate.

Task 1.c) Determine appropriate training scenarios to cover skill levels of various individuals.

<u>Aim 2.</u> Determine how contextual factors in the exam influence diagnosis decision-making.

Task 2.a) Setup contextual scenarios.

<u>Task 2.b)</u> Setup human-like aspects of standardized patient in simulated training environment.

<u>Aim 3.</u> Determine methods to customize performance assessment and training intervention.

<u>Task 3.a)</u> Setup assessment based first on "up-down" or computerized adaptive testing (CAT) strategies.

Task 3.b) Determine training interventions and levels of feedback.

<u>Aim 4.</u> Determine if applied finger techniques correlate with level of performance.

Task 4.a) Correlate general aspects of technique with measures of assessment.

<u>Task 4.b)</u> Correlate technique patterns of experts and novices with measures of performance assessment.

(Task 5) Plan for interaction with EVMS and U.Va. Biomaterials

Timeline for Completion of Major Tasks

Year	2	00		2009												2	2010											2011									
Task	N	1J	J	Α	S	O	Ν	D	J	F	M	Α	M	J	J	Α	S	0	Ν	D	J	F	M	Α	M	J	J	Α	S	O	Ν	D	J	F	M	Α	M
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Body

<u>Aim 1</u> seeks to determine distinct skill levels for discernment of palpable characteristics.

<u>Task 1.a</u> is to characterize anatomical attributes and pathological stages of disease. Graduate student William Carson is working in this area. Following first year work to build the indenter and begun validating it with silicone-elastomer samples, we have continued to collect data in the clinic with normal autopsied prostates at U.Va and cancerous prostates at EVMS. This data has since been analyzed, formed into a publication and accepted by the journal Medical Engineering and Physics. I attach below this abstract for this journal article listed in *Key Research Accomplishments* below.

Overall, the work in Task 1.a has sought to characterize the material properties of prostate tissue, removed post-surgery, and indented with a custom-built spherical indenter. mechanical characterization of prostate tissue has not received much attention and is often disconnected from the clinic, where samples are readily attained. This work sought to inform the realistic design of artificial tissue – and also to relate material properties with disease states. We developed a spherical indenter to generate force-displacement data from ex vivo tissue. both whole mount and 5 mm cross-sections. Indentation velocity, depth, and sphere diameter, and four means of estimating elastic modulus (EM) were validated. EM was then estimated for 26 prostate specimens obtained from radical prostatectomy and 6 samples obtained from autopsy. Specimens were obtained in conjunction with Dr. Tracey Krupski (Urology, U.Va.) and Dr. O. John Semmes (Urology, Eastern Virginia Medical School). Prostatectomy prostates were also evaluated clinically upon digital rectal exam and pathologically post-extirpation. Overall, this work found that diseased prostate tissue is stiffer than normal tissue, stiffness increases with disease severity, and a large variability exists between samples, even though disease differences within a prostate are detectable. We compared these measurements with those of simulated prostate tissues and found that the two coincide, in terms of gross stiffness. We now seek to evaluate more complex hyperelastic and viscoelastic properties which are more difficult to compare for a large number of samples.

Background - The mechanical characterization of prostate tissue has not received much attention and is often disconnected from the clinic, where samples are readily attained. Methods - We developed a spherical indenter for the clinic to generate forcedisplacement data from ex vivo prostate tissue. Indentation velocity, depth, and sphere diameter, and four means of estimating elastic modulus (EM) were validated. EM was then estimated for 26 prostate specimens obtained via prostatectomy and 6 samples obtained from autopsy. Prostatectomy prostates were evaluated clinically upon digital rectal exam and pathologically post-extirpation. *Findings* – Whole-mount measurements yielded median EM of 43.2 kPa (SD = 59.8 kPa). Once sliced into cross-sections, median EM for stage T2 and T3 glands were 30.9 and 71.0 kPa, respectively, but not significantly different. Furthermore, we compared within-organ EM difference for prostates with (median = 46.5 kPa, SD = 22.2 kPa) and without (median = 31.0 kPa, SD = 63.1 kPa) palpable abnormalities. Interpretation - This work finds that diseased prostate tissue is stiffer than normal tissue, stiffness increases with disease severity, and large variability exists between samples, even though disease differences within a prostate are detectable. A further study of late-stage cancers would help to strengthen the findings presented in this work.

We are also in the process of writing a second paper "Authenticating a high fidelity prostate exam simulator." Which is to be submitted in the future to the Journal of Urology. We are

currently collecting data with urologists at Uva for this work. The main idea to be presented in this publication in progress is first to justify our hypothesis that tissue elasticity is indicative of carcinomous changes by correlating DRE findings with tissue elasticity and histopathology. Second, we would seek to employ urologic surgeons to evaluate our prostate simulator in three ways: 1) authenticate that the elasticity of the simulated prostates accurately represents the range of normal prostate stiffness, 2) determine the range of nodule size reasonably palpable by DRE, and 3) discern what degree of elasticity difference within the same prostate suggests malignancy.

<u>Task 1.b</u> is to determine the range of disease states that are palpable and simulate. Graduate student Leigh Baumgart worked in this area in year 1. Last reporting period, I included a draft abstract for a journal article listed in *Key Research Accomplishments* below. This work has since been accepted by the Journal of Cancer Epidemiology. Its abstract is attached below.

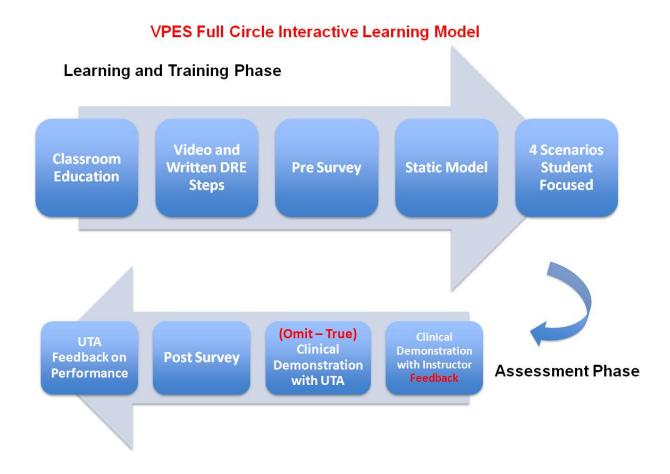
Overall, this work has sought to understand the perceptible limits of the DRE, which are based on some unresolved combination of the size, depth, and hardness of abnormalities within a given prostate stiffness. Journal paper 9 is included in this packet. This work seeks to inform the range of disease states that are palpable, from human sensory limits. Using a custom-built device similar to the VPES, an 18 participant human-subjects study was conducted that simulated the four aforementioned conditions. Within silicone-elastomers that mimic normal prostate tissue, only abnormalities of diameter greater than 4 mm (20 mm³ in volume) were consistently detectable (above 75% of the time) at the shallowest depth (5 mm). In contrast, abnormalities located in simulated tissue of greater stiffness (82 kPa compared to 21 kPa) must be twice that volume. Overall, the study found that size and depth of abnormalities most influence detectability, while the relative hardness between abnormalities and tissue affects detectability for some size-depth combinations.

Background: Although the digital rectal exam (DRE) is a common method of screening for prostate cancer and other abnormalities, the limits of ability to perform this hands-on exam are unknown. Perceptible limits are a function of the size, depth, and hardness of abnormalities within a given prostate stiffness. Methods: To better understand the perceptible limits of the DRE, we conducted a psychophysical study with 18 participants using a custom-built apparatus to simulate prostate tissue and abnormalities of varying size, depth, and hardness. Utilizing a modified version of the psychophysical method of constant stimuli, we uncovered thresholds of absolute detection and variance in ability between examiners. Results: Within silicone-elastomers that mimic normal prostate tissue (21 kPa), abnormalities of 4 mm diameter (20 mm³ volume) and greater were consistently detectable (above 75% of the time) but only at a depth of 5 mm. Abnormalities located in simulated tissue of greater stiffness (82 kPa) had to be twice that volume (5 mm diameter, 40 mm³ volume) to be detectable at the same rate. Conclusions: This study finds that the size and depth of abnormalities most influence detectability, while the relative stiffness between abnormalities and substrate also affects detectability for some size/depth combinations. While limits identified here are obtained for idealized substrates, this work is useful for informing the development of training and allowing clinicians to set expectations on performance.

Further work using logistic regression analyzed the relative importance of each factor and their interactions. This work formed the basis for a second publication, which was accepted for and presented at the Proceedings of the 2010 IEEE Haptic Interfaces for Virtual Environment and Teleoperator Systems.

Softness discrimination and the detection of inclusions are important in surgery and other medical tasks. To better understand how the characteristics of an inclusion (size, depth, hardness) and substrate (stiffness) affect their tactile detection and discrimination with the bare finger, we conducted a psychophysics experiment with eighteen participants. The results indicate that within a more pliant substrate (21 kPa), inclusions of 4 mm diameter (20 mm³ volume) and greater were consistently detectable (above 75% of the time) but only at a depth of 5 mm. Inclusions embedded in stiffer substrates (82 kPa) had to be twice that volume (5 mm diameter, 40 mm³ volume) to be detectable at the same rate. To analyze which tactile cues most impact stimulus detectability, we utilized logistic regression and generalized estimating equations. The results indicate that substrate stiffness most contributes to inclusion detectability, while the size, depth, and hardness of the stimulus follow in individual importance, respectively. The results seek to aid in the development of clinical tools and information displays and more accurate virtual haptic environments in discrimination of soft tissue.

<u>Task 1.c</u> began this reporting period. Reba Childress and Greg Gerling brought in a nursing student (Petheree) to help us develop the scenarios. We are using these scenarios to create the VPES Full Circle Interactive Learning Model to allow the integration of VPES simulator training into the Medical & Nursing Curricula. The figure below delineates the major training steps as envisioned (though the work is currently under development.



With this framework in places, we are developing scenarios for BPH, Prostatitis, Carcinoma and normal cases, following the example that can be observed in the 3 figures that follow.

Patient Information



Age: 52

Race: African-American

Past Medical History: Diabetes Hypertension Hyperlipidemia

Family Hx/Social Hx:

Uncle died with Prostate Cancer

Father has Prostate Cancer

Patient smokes 1 pack of cigarettes per day, smoker x30 years

History of Present Illness:

Patient presented to clinic with complaint of dysuria, hematuria and a weak flow during urination. PSA levels returned at 22

This information is given BEFORE VPES simulator used by student

Physical Findings

Symptomatic – weight loss, frequent urination

Recommendation and Education

Ultrasound Biopsy recommended

Decrease high fat and high protein in diet, these may alter vitamin A absorption thus increasing Cancer risk

Eat plenty of:

•Fruits,

•vegetables

·whole grains

Limit intake of:

•Red meats (beef, pork, lamb) •high fat or processed meats (luncheon meats, hot dogs,

bacon)

Establish and maintain healthy weight

Discuss with healthcare provider about whether medicine needed

Debriefing:

How do you think your DRE examination went?

How can you improve patient comfort? Your comfort as examiner?

What were the findings?

What are some symptoms of prostate cancer?

How is it treated?

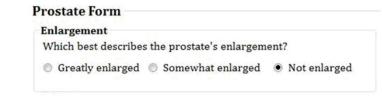
What would you suggest as the plan of care for this patient?

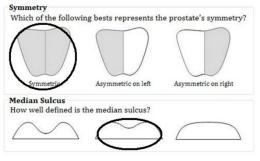
What have you taken away from this experience?

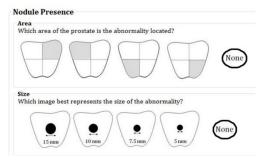
Student should state findings DURING simulation

AFTER simulation completed, student will synthesize and Integrate (omit – assess) patient information and findings to create recommendations and education for patient.

VPES Presentation - Prostate CA







<u>Aim 2</u> seeks to determine how contextual factors in the exam influence diagnosis decision-making.

<u>Task 2.a</u> is to setup contextual scenarios. We have continued past our previous preliminary development of user interface concepts. This has been combined in our description of Task 1.c because of the similarities in tasks and shown above. In the previous year we developed user interface concepts. Those concepts will be put into implementation as soon as Task 1.c narrows the scope of the scenarios and general flow and usage of the device, a necessary prerequisite.

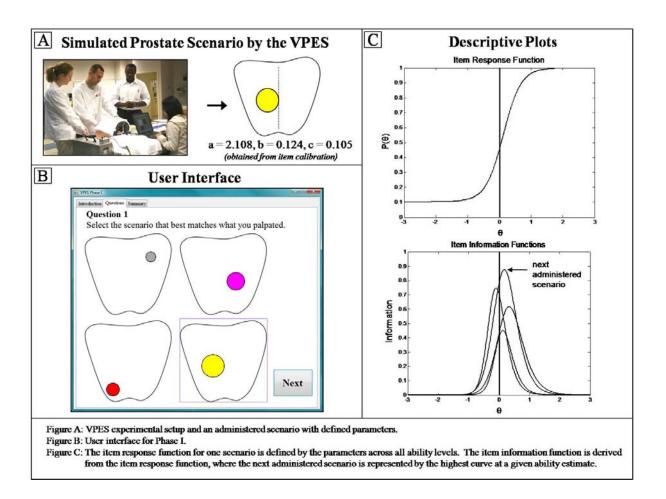
<u>Task 2.b</u> will begin in the third year. It is the only task that is behind schedule, but this is not seen as a critical issue, compared to the other tasks. It seeks to setup human-like aspects of standardized patient in simulated training environment. Essentially it involves the creation of a rectal wall that is dynamically moving.

<u>Aim 3.</u> seeks to determine methods to customize performance assessment and training intervention.

<u>Task 3.a</u> is to setup assessment based first on "up-down" or computerized adaptive testing (CAT) strategies. Graduate student Angela Lee is working in this area. The following is a synopsis of the direction taken so far in this task. She presented this year at Simulation in Healthcare a poster entitled "Applying Computerized Adaptive Testing to the Virginia Prostate Examination Simulator" and this abstract is given below.

This task, in progress, seeks to develop an efficient and accurate means of assessing the palpation skill of trainees. We are integrating computerized adaptive testing (CAT) with the VPES to provide proficiency estimates with fewer test items, thereby reducing testing duration. The main components in our CAT exam are to develop an item bank of prostate scenarios, implement the item response theory (IRT) and an item selection procedure, and determine the stopping criteria and scoring method. Using a three parameter logistic model, the developed computer algorithm will selectively choose subsequent prostate scenarios based on responses to previous scenarios. The three parameters that characterize each scenario are difficulty, item discrimination, and guessing parameters. To validate the CAT application, a set of two experiments will be conducted. The first hypothesis is that low performers will be differentiable from high performers. The second hypothesis is that the assessment made in experiment 2 will equal that of experiment 1 but be achieved within a reduced time period, of approximately 25 to 50%.

Introduction. The digital rectal examination (DRE) is a screening method used for the early diagnosis of prostate abnormalities. The Virginia Prostate Examination Simulator (VPES) can administer over 200 scenarios, which creates an unreasonable assessment timeframe. Therefore, we propose to integrate the methodologies underlying a computerized adaptive test (CAT) with the VPES to enable an assessment of DRE palpation skills using fewer scenarios. CAT assesses the ability of an examinee in a reduced timeframe by adapting subsequent scenarios to one's skill level. This iterative process continues until a final estimate of one's ability is determined. Methods. Human subject experiments will be run to test the implementation of CAT with the VPES. During Phase I, 200 scenario questions will be administered using the VPES in a multiple choice format, where the participant matches what they palpated to one of the four choices displayed on the screen. The 200 scenarios represent the CAT item bank. After the responses are dichotomously scored, item calibration software will generate ability estimates (θ) and three parameters (discrimination (a), difficulty (b), and guessing (c)) that characterize each scenario necessary for CAT development. During Phase II, the same participants will return to test the algorithm, where the same scenarios will be administered, but each scenario will be dependent on the response to the previous question. This study was approved by the local IRB. Results. The software for Phase I is complete and an item bank of 200 scenarios was defined within perceptual limits. A preliminary experiment was conducted for Phase I to characterize a subset of the scenarios and to test calibration software. The CAT algorithm will be implemented when parameters for each scenario is obtained from Phase the Discussion/Conclusions. Integrating CAT with VPES can potentially improve the quality of skills assessment in DRE simulators.



<u>Task 3.b</u> has begun this year. Its description has been combined with Task 3.a above since the computerized adaptive test does adapt questions for learners of various levels.

Aim 4. seeks to determine if applied finger techniques correlate with level of performance.

<u>Tasks 4.a and 4.b</u> are to correlate general aspects of technique with measures of performance assessment and correlate technique patterns of experts and novices with measures of performance assessment. Graduate student Ninghuan "Miki" Wang worked in this area, along with undergraduate student Tashima Lambert. Two journal articles based on work done mostly in reporting period 1 have been since published and listed in *Key Research Accomplishments* below.

Overall, the study done with 16 resident physicians and 18 nurse practitioner students algorithmically defined a set of finger palpation techniques for the digital rectal exam (DRE) based upon past qualitative definitions of hands-on technique and evaluated performance between experts and novices. Four palpation techniques were defined: global finger movement, local finger movement, and average intentional finger pressure, and dominant intentional finger frequency. Streaming feedback from force and balloon sensors in the instrumented prostate provided the source data. With this information we sought to assess if certain techniques were prevalently used and correlated with greater performance accuracy. Although technique utilization varied, some elements clearly impacted performance. For example, those utilizing the local finger movement of vibration (i.e., firm pressure of varying intensity) were significantly better at detecting abnormalities. Also, the V pattern of global finger movement led to greater success and average finger pressure of greater magnitude was required to detect smaller, more deeply positioned abnormalities. We found that the quantified palpation techniques appear to account for examination ability at some level but not entirely for differences between experience levels.

Abstract for paper in IEEE Transactions on Information Technology in Biomedicine

This work seeks to quantify finger palpation techniques in the prostate clinical exam, determine their relationship with performance in detecting abnormalities, and differentiate the tendencies of nurse practitioner students and resident physicians. One issue with the digital rectal examination (DRE) is that performance in detecting abnormalities varies greatly and agreement between-examiners is low. The utilization of particular palpation techniques may be one way to improve clinician ability. Based on past qualitative instruction, this work algorithmically defines a set of palpation techniques for the DRE, i.e., global finger movement, local finger movement, and average intentional finger pressure, and utilizes a custom-built simulator to analyze finger movements in an experiment with two groups: 18 nurse practitioner students and 16 resident physicians. Although technique utilization varied, some elements clearly impacted performance. For example, those utilizing the local finger movement of vibration were significantly better at detecting abnormalities. Also, the V global finger movement led to greater success, but finger pressure played a lesser role. Interestingly, while the residents were clearly the superior performers, their techniques differed only subtly from the students. In summary, the quantified palpation techniques appear to account for examination ability at some level but not entirely for differences between groups.

Abstract for paper in Journal of Simulation in Healthcare

Introduction: Prostate carcinoma (and other prostate irregularities and abnormalities) are detected in part via the digital rectal exam. Training clinicians to use particular palpation techniques may be one way to improve rates of detection. Methods: In an experiment of

34 participants with clinical backgrounds, we used a custom-built simulator to determine if certain finger palpation techniques improved one's ability to detect abnormalities smaller in size and dispersed as multiples over a volume. The intent was to test abnormality cases of clinical relevance near the limits of size perceptibility (i.e., 5 mm diameter). The simulator can present abnormalities in various configurations and record finger movement. To characterize finger movement, four palpation techniques were quantitatively defined (global finger movement, local finger movement, average intentional finger pressure, and dominant intentional finger frequency) to represent the qualitative definitions of other researchers. Results: Participants who used more thorough patterns of global finger movement (V and L) ensured the entire prostate was searched and detected more abnormalities. A higher magnitude of finger pressure was associated with the detection of smaller abnormalities. The local finger movement of firm pressure with varying intensity was most indicative of success and was required to identify the smallest (5 mm diameter) abnormality. When participants utilized firm pressure with varying intensity, their dominant intentional finger frequency was about 6 Hz. Conclusions: The use of certain palpation techniques does enable the detection of smaller and more numerous abnormalities, and we seek to abstract these techniques into a systematic protocol for use in the clinic.

We have since begun a study with collaborator Tracey Krupski to evaluate the finger patterns of expert urologist examiners and this work will be presented next reporting period, once that study is complete. Testing with 12 urological clinicians is currently underway to determine if there is a standard palpation technique. If such a palpation technique does exist, the potential exists for a high yield training intervention.

<u>Task 5</u> is to setup the interaction with EVMS and U.Va. Biomaterials. Task 5 was completed in year 1. We have IRB agreements in place at the University of Virginia and Eastern Virginia Medical School. These have also been approved by the IRB of the Department of Defense.

Key Research Accomplishments

We list several journal and conference publications, either already presented, currently under review, or to be submitted in the next 2-3 months.

Peer-reviewed publications accepted

- 1. <u>Baumgart, L.A.</u>, Gerling, G.J., and Bass, E.J. Characterizing the range of simulated prostate abnormalities palpable by digital rectal examination, Cancer Epidemiology, 34 (1): 79-84 2010
- 2. <u>Wang, N.</u>, Gerling, G.J., Moyer Childress, R., and Martin M.L. Quantifying palpation techniques in relation to performance in a clinical prostate exam, IEEE Transactions on Information Technology in Biomedicine, *in press*
- 3. Wang, N., Gerling, G.J., Moyer Childress, R., and Martin M.L. Using a prostate exam simulator to decipher palpation techniques that facilitate abnormality detection near clinical limits, Simulation in Healthcare: The Journal of the Society for Simulation in Healthcare, 5(3):152-160 2010
- 4. <u>Carson, W.C.</u>, Gerling, G.J., Krupski, T.L., Gundersen, C.A., Harper, J.C., and Moskaluk, C.A., Material characterization of *ex vivo* prostate tissue via spherical indentation in the clinic, Medical Engineering & Physics, *accepted*

Peer-reviewed publications in progress

- 1. Gerling, G.J., Moyer Childress, R. and Martin, M.L., Designing a clinically functional simulator to support effective learning: features and cases. Planned submission to Medical Teacher.
- 2. Kowalik, C.G., <u>Lee, A.J.</u>, <u>Carson, W.C.</u>, Gerling, G.J., Harper, J.C., Moskaluk, C.A., and Krupski, T.L., Authenticating a High Fidelity Prostate Exam Simulator. Planned submission to Journal of Urology.

Conference papers and presentations (peer-reviewed)

- Wang, N., Gerling, G.J., Moyer Childress, R., and Martin M.L. Characterizing finger palpation in the detection of prostate cancers and abnormalities. Proceedings of the Human Factors and Ergonomics Society 52nd Annual Meeting, 2008, New York City, NY, pp. 813-817
- 2. <u>Baumgart, L.A.</u>, Gerling, G.J., and Bass, E.J., Psychophysical detection of inclusions with the bare finger amidst softness differentials, Proceedings of the 2010 IEEE Haptic Interfaces for Virtual Environment and Teleoperator Systems, Boston, MA, pp 17-20 2010 (acceptance rate: 42%)

Student conferences (not rigorously peer-reviewed)

- 1. <u>Baumgart, L.A.</u>, Gerling, G.J. & Bass, E.J., Characterizing the range of simulated prostate abnormalities palpable by digital rectal examination. Presented at the NLM Informatics Training Conference (July 23-24, 2009) Portland, Oregon
- 2. <u>Lee, A.J.</u>, Gerling, G.J., Applying computerized adaptive testing to the Virginia prostate examination simulator, Works in Progress Abstract and Poster Presentation at the 10th Annual International Meeting on Simulation in Healthcare (Jan. 23-27, 2010) Phoenix, Arizona.

- 3. <u>Baumgart, L.A.</u>, Gerling, G.J. and Bass, E.J., Characterizing the range of simulated prostate abnormalities palpable by digital rectal examination, Abstract and Poster Presentation for Academy of Distinguished Educators 6th Medical Education Research Day and Poster Session (February 22-26, 2010) U.Va. School of Medicine
- Lee, A.J., Gerling, G.J., Applying computerized adaptive testing to the Virginia prostate examination simulator, Abstract and Poster Presentation for Academy of Distinguished Educators – 6th Medical Education Research Day and Poster Session (Feb. 22-26, 2010) U.Va. School of Medicine
- 5. Gundersen, C.A., Gerling, G.J., <u>Carson, W.C.</u>, Thomas, K.R., Harper, J., Moskaluk, C.A., Krupski, T.L., Assessing mechanical properties of benign and malignant prostate tissue. American Society of Clinic Oncology 2010, Chicago, Illinois (Published Abstract, Permanent Abstract ID: e15109)

Students graduated

Ninghuan Wang (Master of Science, May 2009)

Reportable Outcomes

Several papers have now been peer reviewed. Those are listed above.

Conclusions

This is our second annual report. Our team has made good progress on our three year grant toward achieving aims. In the last year, we had 4 journal and 2 peer-reviewed conference papers accepted, and have others near completion. We also had other presentations that were not peer reviewed. We have collected data from several human-subjects experiments and also tissue measurement experiments. We have subsequently analyzed that data via new procedures and algorithms developed, have worked on the development of a curriculum framework in which to embed the simulator in practice, and continued work in formulating an algorithm to allow computerized adaptive testing principles to be applied to reduce simulation exam duration. We will continue to work toward aim completion over the final year of the grant.

References

None applicable.

Appendices

None applicable.